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TRAIN study: TRAnsfusion In Neonates and ideal red cell volume study

Submission date	**Recruitment status**	[X] Prospectively registered
27/11/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/01/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/08/2020	Neonatal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Some newborn babies require blood transfusion (a process that involves taking blood from one person and giving it to someone else), especially those who are born early and/or with very low birth weight. Babies who are full term but very sick may also require blood transfusion. Oxygen is transported from the lungs to the tissues through special type of cells called Red Blood Cells (RBCs). These cells contain a substance called Haemoglobin (Hb) which carries oxygen. When babies are sick it is presumed for their organs to function normally Hb has to be maintained at certain levels depending how sick they are. This level is called the desired or target Hb level. It is quite common for sick babies Hb to decrease for several reasons and they may need their Hb to be topped up . Usually this is done by transfusing RBCs into the circulation. The current practice at present is that babies receive 20 ml/kg of RBC if they are low on Hb. This method of calculating the required volume does not consider level of anaemia (low Hb). Another method which considers the level of anaemia in determining the volume (amount) of RBCs to give is used in older children. The aim of this study is to compare both methods and see which one is more likely to raise Hb level to the desired targets.

Who can participate?
Babies who require blood transfusion for the first time and were born prematurely (less than 32 weeks gestation).

What does the study involve?
Babies are randomly allocated to one of two groups: one group of babies will receive RBCs based on standard practice (based on weight only) while the other group will receive RBCs based on weight and level of anaemia (Hb). Hb level will be measured after transfusion to see if the desired target has been reached.

What are the possible benefits and risks of participating?
This study will help us to determine which method is better in estimating the required volume to transfuse, and by reaching the desired Hb target from the first transfusion baby will avoid a second transfusion. There are no additional risks from participation beside the standard risks of blood transfusion.

Where is the study run from?
The study is run by the Neonatology Department, National Maternity Hospital, Ireland.

When is the study starting and how long is it expected to run for?
The study started in May 2014 and is expected to run for one year.

Who is funding the study?
Neonatology Department, National Maternity Hospital, Ireland.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
TRAIN study: TRAnsfusion In Neonates and ideal red cell volume study - a randomised controlled study

Acronym
TRAIN

Study objectives
Using a formula based on infant weight and degree of anaemia, to calculate required red blood cells (RBC) transfusion volume, is more likely to achieve desired target haemoglobin (Hb) level within 24 hours post transfusion, in comparison to the current practice in our neonatal intensive care unit (NICU) (10 ml - 20 ml/kg).

On 05/08/2014 the following changes were made to the trial record:
1. The scientific title was changed from 'TRAIN study: TRAnsfusion In Neonates and ideal red cell volume study a randomised controlled double blinded study' to 'TRAIN study: TRAnsfusion In Neonates and ideal red cell volume study - a randomised controlled study'.
2. The study design was changed from 'Randomised controlled double blinded single centre study' to 'Randomised controlled single-centre study'.
3. The anticipated start date was changed from 01/02/2014 to 01/05/2014.
4. The anticipated end date was changed from 30/01/2015 to 01/06/2015.
5. The target number of participants was changed from 90 to 66.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee in the National Maternity Hospital (Ireland), February 2014

Study design
Randomised controlled single-centre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Transfusion for anaemia of prematurity

Interventions
Comparing standard method to calculate RBC volume to transfuse (10 - 20ml/kg) to a formula that includes desired rise in Hb level (volume of packed cell transfused (ml) = 5 X weight (kg) X desired rise in Hb (g/dl)). The main outcome of the study is determine which method of calculating RBC transfusion volume is more likely to achieve the target Hb level. One arm will include neonates where volume is calculated using the standard method, which is based only on weight (ml/kg). The other arm will include neonates who receive a volume calculated using weight and desired rise in Hb. Duration of intervention is maximum 4 hours, which is the duration of transfusion. Neonates will be followed for a period of 2 weeks to determine the rise in Hb post transfusion and the need to re-transfuse.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 05/08/2014:
Reaching desired Haemoglobin level within 16 hours post transfusion

Previous primary outcome measures:
Hemoglobin/Hematocrit (Hb/HCT) rise within 24 hours post transfusion

Key secondary outcome(s))
Current secondary outcome measures as of 05/08/2014:
1. Re-transfusion within two weeks after the first transfusion
2. Transfusion-associated circulatory overload (TACO)
3. Use of diuretics during or post transfusion
4. Oxygen requirement (before and after transfusion)
5. Incidence:
5.1. Necrotising entero-colitis (NEC)
5.2. Chronic lung disease (CLD)
5.3. Retinopathy of prematurity (ROP)
5.4. Peri-ventricular leukomalacia (PVL)
5.5. Intra-ventricular haemorrhage (IVH)
5.6. Bayley's scales of infant development at 2 years
5.7. Mortality

Previous secondary outcome measures:
1. Re-transfusion within two weeks after the first transfusion
2. Transfusion Associated Circulatory Overload (TACO) within 24 hours of transfusion
3. Use of diuretics due to volume overload within 24 hours of transfusion
4. Oxygen requirement pre and post transfusion within 24 hours using pulse oximeter

Completion date
01/06/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/08/2014:
1. All infants admitted to NICU and requiring RBC transfusion for the first time
2. Born less than 32 weeks gestation

Previous inclusion criteria:
All infants admitted to NICU and required RBC transfusion for the first time.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment

63

Key exclusion criteria
Current exclusion criteria as of 05/08/2014:
1. Evidence of active bleeding
2. 24-hour post surgical intervention
3. ABO/Rh incompatibility haemolysis
4. Disseminated Intravascular Coagulopathy
5. Intra-Ventricular Haemorrhage (IVH) grade III or more

Previous exclusion criteria:
1. Evidence of bleeding
2. 24 h post surgical intervention
3. ABO/Rh incompatibility haemolysis and/or
4. Disseminated Intravascular Coagulopathy

Date of first enrolment
01/05/2014

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Neonatology Department
Dublin
Ireland
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Sponsor information

Organisation
National Maternity Hospital (Ireland)

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
National Maternity Hospital (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration